UNITED STATE DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JAMIA FERNANDES and THOMAS NAGLER, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. CENTESSA PHARMACEUTICALS PLC, SAURABH SAHA, GREGORY WEINHOFF, MARELLA THORELL, FRANCESCO DE RUBERTIS, ARJUN GOYAL, AARON KANTOFF, BRETT ZBAR, MARY LYNNE HEDLEY, SAMARTH KULKARNI, CAROL STUCKLEY, ROBERT CALIFF, MORGAN STANLEY & CO. LLC, and GOLDMAN SACHS & CO. LLC, Defendants.	Case No. 1:22-cv-08805-GHW-SLC Hon. Gregory H. Woods CLASS ACTION **[CORRECTED] AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** DEMAND FOR JURY TRIAL

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Co-Lead Plaintiffs Jamia Fernandes and Thomas Nagler ("Plaintiffs"), individually and on behalf of all others similarly situated, by and through their undersigned attorneys ("Co-Lead Counsel"), bring this class action against Centessa Pharmaceuticals plc. ("Centessa" or the "Company"), its Chief Executive Officer ("CEO") and Director Saurabh Saha, its Chief Financial Officer ("CFO") Gregory Weinhoff, its Directors Marella Thorell, Francesco De Rubertis, Arjun Goyal, Aaron Kantoff, Brett Zbar, Mary Lynne Hedley, Samarth Kulkarni, Carol Stuckley, and Robert Califf, and the lead underwriters of its IPO offering, Morgan Stanley & Co. LLC and Goldman Sachs & Co. LLC.

Plaintiffs allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by Plaintiffs' attorneys which included, among other things, a review of Defendants' public documents, conference call transcripts and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and concerning Centessa, analysts' reports and advisories concerning Centessa, and information readily obtainable on the Internet.

Co-Lead Counsel's investigation into the matters alleged herein is continuing, and many relevant facts are known only to, or are exclusively within the custody or control of, Defendants. Plaintiffs believe that substantial, additional evidentiary support will exist for the allegations set forth herein after reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all persons and entities other than Defendants that purchased or otherwise acquired Centessa American Depository Shares ("ADSs") pursuant and/or traceable to the Registration Statement (defined below) issued in connection with the Company's initial public offering conducted on or about May 28, 2021 (the

"IPO" or the "Offering") and who were damaged thereby (the "Class"). Excluded from the Class are: (a) Defendants and their immediate families; (b) current and former directors or officers of Centessa or any of its predecessors or subsidiaries; and (c) any entity controlled, majority-owned or wholly owned, or affiliated with any of the above. Plaintiffs' Complaint asserts claims against the Defendants under Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act") arising from Defendants negligence and does not allege fraud.

2. Centessa is a pharmaceutical research and development ("R&D") company, formed in October 2020 by Medicxi, a life-sciences focused international investment firm based in the United Kingdom.

3. On April 21, 2021, Centessa filed a registration statement on Form S-1 with the SEC in connection with the IPO, which, after several amendments, was approved by the SEC on May 27, 2021 (the "Registration Statement"). On or about May 28, 2021, Centessa conducted its IPO, issuing 16.5 million of its ADSs to the public at $20.00 per ADS, for total proceeds to the Company of $306.9 million after expenses and underwriting discounts.

4. At the time of the IPO, Centessa's most important drug candidate, lixivaptan, was one of only four drug candidates that the Company had in development and its only drug to reach Phase 3 clinical development. Lixivaptan was being developed to treat autosomal dominant polycystic kidney disease ("ADPKD"), "the fourth leading cause of kidney failure in the U.S. and one of the most common inherited genetic diseases in humans, occurring equally in women and men, in all races, globally."

5. As described more fully herein, Defendants falsely represented in the Registration Statement that data from various studies supported the Company's claim that lixivaptan would have a more favorable liver safety profile than a competitor drug, tolvaptan. Tolvaptan, the only

drug then approved by the FDA to treat ADPKD, was associated with adverse events involving elevated liver enzymes in patients with ADPKD. Centessa claimed that lixivaptan would be as efficacious as tolvaptan in treating ADPKD but without the associated risk of liver toxicity—a key to the commercial viability of lixivaptan. But Centessa failed to disclose critical facts about these studies which did not support Defendants' representations that lixivaptan had a better liver safety profile and, thus, the market was misled into believing the drug had significantly greater commercial potential than the evidence supported.

6. Specifically, Centessa failed to disclose that it took at least three months for patients on tolvaptan to exhibit critical levels of liver enzyme elevation and, even then, such levels were only observed in patients with ADPKD. These omissions were materially misleading because the clinical trials Centessa cited and relied on as "the most useful safety data" supporting lixivaptan's purported favorable safety profile, had a mean duration of exposure to the drug of just 27.5 days and involved only non-ADPKD patients—and thereby provided ***no*** useful safety data differentiating lixivaptan from tolvaptan for the treatment of ADPKD. The other human trials and simulations Defendants cited in support likewise were too short and/or did not involve an ADPKD population. Thus, Defendants' claims that lixivaptan had a differentiated safety profile from tolvaptan lacked any reasonable basis.

7. In addition, with respect to lixivaptan's clinical and commercial prospects, Centessa failed to disclose that, at the time of the IPO, the Company was already seeing signs of weak demand from both patients and doctors as it struggled to enroll participants in its ongoing Phase 3a ALERT trial. Indeed, at the time of the IPO, nine months after beginning enrollment, Centessa had only two of its targeted 50 patients enrolled in the Phase 3a ALERT trial.

8. On June 2, 2022, Centessa issued a press release announcing the discontinuation of lixivaptin, following an observation of elevated liver enzyme levels in one subject in its Phase 3a safety study (the "ALERT Study"), which was designed to assess liver safety. Following this news, Centessa's ADS price fell $1.25 per share, or 27.78%, to close at $3.25 per share that day.

II. JURISDICTION AND VENUE

9. This action arises under Sections 11 and 15 of the Securities Act of 1933 (15 U.S.C. §§ 77k and 77o) (the "Securities Act").

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act, codified at 15 U.S.C. §78aa. In connection with the acts, conduct, and other wrongs alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the U.S. mail, interstate telephone communications, and the facilities of national securities exchanges.

11. Venue is proper in this judicial district pursuant to §22 of the Securities Act, (15 U.S.C. §77v) and 28 U.S.C. §1391(b). Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this judicial district, and Centessa shares traded on an exchange located in this judicial district during the Class Period. The parties have previously stipulated and agreed that venue is proper in recognition of the forum selection clause set forth in the Articles of Association of Defendant Centessa Pharmaceuticals plc. (ECF. No. 9).

A. The Parties

1. Lead Plaintiffs

12. Lead Plaintiffs Jamia Fernandes and Thomas Nagler purchased or acquired the Centessa ADSs set forth in their sworn certifications previously filed with this Court, ECF Nos.

29-1 and 33-3, at artificially inflated prices pursuant or traceable to the IPO and suffered damages as a result of Defendants' violations of the federal securities laws, alleged herein.

2. Defendants

13. Defendant Centessa is organized under the laws of England and Wales with principal executive offices located at 3rd Floor, 1 Ashley Road, Altrincham, Cheshire WA14 2DT, United Kingdom. The Company's ADSs trade in an efficient market on the NASDAQ under the trading symbol "CNTA."

15. Defendant Saurabh Saha ("Saha") served as CEO and Director of Centessa at all relevant times hereto. Defendant Saha also has prior research experience concerning the use of vaptans for the treatment of polycystic kidney disease, and conducted an animal study and published an article on the topic in BMC Nephrology as early as 2013.[1] Defendant Saha signed the negligently prepared, false and misleading Registration Statement filed with the SEC.

16. Defendant Gregory Weinhoff ("Weinhoff") served as Centessa's CFO at all relevant times hereto. Defendant Weinhoff signed the negligently prepared, false and misleading Registration Statement filed with the SEC.

17. Defendant Marella Thorell ("Thorell") served as Centessa's Chief Accounting Officer at all relevant times until July 31, 2022. Prior to that, Defendant Thorell served as Head of Finance at Centessa since February 2021 and as Chief Financial Officer of Palladio Biosciences from October 2019 to January 2021. Defendant Thorell signed the negligently prepared, false and misleading Registration Statement filed with the SEC.

[1] Roix, Jeffrey and Saha, Saurabh, *TNF-α Blockade Is Ineffective in Animal Models of Established Polycystic Kidney Disease*. BMC NEPHROL 14, 233 (2013), https://doi.org/10.1186/1471-2369-14-233.

18. Defendant Francesco De Rubertis ("De Rubertis") served as Director of Centessa and Chairman of Centessa's Board of Directors at all relevant times hereto. Defendant De Rubertis was also the co-Founder at Medicxi and a Partner there from its inception in 2016. Per the Registration Statement, Defendant De Rubertis is "qualified to serve on [Centessa's] board of directors because of his experience as a seasoned investor in the industry in which [the Company] operate[s]." Defendant De Rubertis authorized the signing of the negligently prepared, false and misleading Registration Statement filed with the SEC.

19. Defendant Arjun Goyal ("Goyal") served as Director at Centessa at all relevant times hereto. Defendant Goyal authorized the signing of the negligently prepared, false and misleading Registration Statement filed with the SEC.

20. Defendant Aaron Kantoff ("Kantoff") served as Director at Centessa at all relevant times until July 1, 2022. Defendant Kantoff was also a Venture Partner at Medixci at all relevant times hereto. Defendant Kantoff authorized the signing of the negligently prepared, false and misleading Registration Statement filed with the SEC.

21. Defendant Brett Zbar ("Zbar") served as Director at Centessa at all relevant times hereto. Defendant Zbar authorized the signing of the negligently prepared, false and misleading Registration Statement filed with the SEC.

22. Defendant Mary Lynne Hedley ("Hedley") served as Director at Centessa at all relevant times hereto. Defendant Hedley authorized the signing of the negligently prepared, false and misleading Registration Statement filed with the SEC.

23. Defendant Samarth Kulkarni ("Kulkarni") served as Director at Centessa at all relevant times hereto. Defendant Kulkarni authorized the signing of the negligently prepared, false and misleading Registration Statement filed with the SEC.

24. Defendant Carol Stuckley ("Stuckley") served as Director at Centessa at all relevant times hereto. Defendant Stuckley signed the negligently prepared, false and misleading Registration Statement filed with the SEC.

25. Defendant Robert Califf ("Califf") (collectively with all Defendants, excluding Centessa, Morgan Stanley & Co., LLC, and Goldman Sachs & Co, LLC, the "Individual Defendants") served as Director at Centessa at all relevant times, until February 16, 2022 when he resigned and was confirmed as incoming Commissioner at the U.S. Food and Drugs Administration ("FDA"). Defendant Califf authorized the signing of the negligently prepared, false and misleading Registration Statement filed with the SEC.

26. Under the terms and subject to the conditions in the IPO underwriting agreement, Morgan Stanley & Co. LLC ("Morgan Stanley") and Goldman Sachs & Co. LLC ("Goldman Sachs," and together with Morgan Stanley, the "Underwriter Defendants") were designated the lead underwriters in the IPO. The IPO was a firm commitment underwriting, meaning the underwriters agreed to purchase all of the shares in the IPO and sell them to the investing public. Goldman Sachs and Morgan Stanley severally agreed to purchase, and Centessa and certain pre-IPO stockholders agreed to sell to them, 5,280,000 ADS each, for which the Underwriter Defendants collectively were paid approximately $14.8 million in discounts. Following the close of the IPO, the Underwriter Defendants also fully exercised their option to purchase an additional 2,475,000 ADSs at the IPO price of $20.00 per ADS.

27. Defendant Morgan Stanley served as an underwriter for the IPO.

28. Defendant Goldman Sachs served as an underwriter for the IPO.

29. As underwriters, the Underwriter Defendants, collectively and individually, are liable for material omissions and misstatements contained in the Registration Statement, unless

they can prove that, prior to the IPO, they conducted a reasonable investigation of the Company to ensure that the statements included in the offering documents (*e.g.*, the Registration Statement) contained no material misstatements or omissions of material fact. The Underwriter Defendants failed to fulfill their duty to the investing public in this regard and cannot meet their burden to show adequate investigation under the circumstances.

III. FACTUAL BACKGROUND

A. Centessa Purports to Employ an "Asset-Centric" and "Data Driven" Approach to Capital Allocation to Fund Drug Development

30. Centessa was founded in October 2020 by Medicxi, an international investment firm focused on the life sciences sector. Defendant De Rubertis, co-Founder and Partner at Medicxi, formerly served as a Partner at Index Ventures for nineteen years, where he launched its life sciences practice and implemented its "asset-centric" approach, before separating from Index Ventures in 2016 to launch Medicxi.[2] Defendant De Rubertis is now Chairman of the Centessa Board of Directors.[3]

31. Centessa is a self-described "asset-centric" holding company. Led by De Rubertis, Centessa acquired eleven biotechnology companies in January 2021 from the portfolios of biotechnology investments held by funds affiliated with Medicxi and its sub-advisees.

32. Centessa identified the following three criteria in the Registration Statement for selecting subsidiary companies: (1) advancement of a single program with clear biological rationale, (2) a differentiated product profile, and (3) a team with deep expertise led by a founder-subject matter expert. At the time of the Registration Statement, Centessa's portfolio was a

[2] According to the Registration Statement, Medicxi thereafter continued as a sub-advisor to Index Ventures.

[3] Research and Development | Centessa founder on the company's unique R&D model (https://deep-dive.pharmaphorum.com/magazine/research-and-development-2021/centessa-founder-companys-unique-rd-model/).

composite of immuno-oncology therapies and therapies intended to treat, as Defendant Saha put it, "rare, but not so rare" diseases, i.e., diseases that are technically considered rare but have relatively high incidence rates.

33. At the time of the IPO, Centessa's pipeline consisted of 16 drug programs in various stages of development—four in clinical testing and twelve in the preclinical stage. Only one, lixivaptan, had progressed to Phase 3 testing. The four clinical stage product candidates are outlined in the chart below:

Product Candidate	Subsidiary	Condition For Which Therapy is Intended	Biological Pathway	Stage of Development at IPO
Lixivaptan	Palladio Biosciences	Autosomal dominant polycystic kidney disease (ADPKD)	vasopressin V2 receptor small molecule inhibitor	Ongoing Phase 3a "ALERT" safety study
SerpinPC	ApcinteX	Hemophilia A and B	activated protein C inhibitor	Phase 2a Clinical Development
Imgatuzumab	Pega-One	Cutaneous squamous cell carcinoma (CSCC)	anti-EGFR monoclonal antibody	Expected to enter a potential registrational Phase 2 clinical trial
ZF874	Z Factor	Alpha-1-antitrypsin deficiency (A1ATD)	small molecule chemical chaperone folding corrector of the Z variant of alpha-1-antitrypsin (Z-A1AT)	Phase 1 clinical development

34. In the Registration Statement, the Company summarized its expected allocation of net IPO proceeds of approximately $256.4 million to $296.2 million,[4] plus existing cash of $250 million raised in Series A funding, as follows:

Lixivaptan	$110 million
SerpinPC	$50 million

[4] The underwriters were given the option to purchase 2,475,000 additional ADSs up to 30 days from the date of the prospectus. The upper limit of the IPO proceeds range provided in the Registration Statement is based on whether the underwriters chose to exercise that option.

Imgatuzumab	$60 million
ZF874	$45 million
12 remaining pre-clinical, pipeline programs	$200 million

35. Thus, nearly 90% of the anticipated IPO proceeds were intended to be put toward the four drugs then in the clinical testing phase, with lixivaptan slated to receive the largest individual investment by nearly a factor of two.

36. According to the Registration Statement, Centessa "management retains final authority over resource allocation decisions" among its drug products. To that end, Centessa maintains an executive leadership team consisting of individuals with significant biotechnology and pharmaceutical expertise, thereby enabling the Individual Defendants to make crucial capital allocation decisions in an informed manner. As Defendant Saha stated in a letter appended to the Registration Statement, "The DNA of Centessa is rooted in asset centricity, but the environment in which it flourishes includes enhanced scale, resources and management with deep technical expertise."

37. The Registration Statement further emphasized that the Company "complement[s] the program expertise of [its] founder-subject matter experts with the broad experience of [its] centralized management team." Centessa's management touts its "relentless focus on data-driven decision making" and "judicious capital allocation" as the "core" of an asset-centric model that allows the Individual Defendants to make asset-allocation decisions quickly, thereby differentiating Centessa from competitors. Using its "data driven" model, Centessa operates by the motto "fail fast, and fail early," which purportedly allows the Company to "expeditiously terminate programs when the data do not support advancing a program." Centessa's purported "fail fast, and

fall early" mantra communicated to investors that Centessa would not continue to invest in programs and product candidates without high potential for successful launch.

B. Development of Lixivaptan for ADPKD

1. Background

38. At the time of the IPO, lixivaptan was being developed by Centessa's Palladio subsidiary located in Horsham, Pennsylvania. Lixivaptan is an orally administered selective vasopressin V2 receptor antagonist that had previously been investigated by Cardiokine to treat hyponatremia (low sodium in the blood) in patients with heart disease.[5] Lixivaptan is a member of the class of drugs known as "vaptans," which block the hormone vasopressin from binding to its V2 receptor. Vasopressin is an antidiuretic hormone that maintains water balance by acting on the kidneys and blood vessels and helps control the amount of water the kidneys reabsorb as they filter out waste from the blood. By interfering with the binding of vasopressin at its receptors, vaptans can excrete excessive fluid that causes conditions like hyponatremia.

39. At the time of the IPO, Palladio was developing lixivaptan for the treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD). ADPKD is an inherited genetic disease in which clusters of fluid-filled cysts develop and enlarge on both kidneys. Over time, cyst growth displaces and destroys healthy kidney tissue, leading to decreased kidney function and, eventually, kidney failure. Although rare, ADPKD is one of the most common, life-threatening genetic diseases—affecting nearly one in 1,000 people. According to Centessa, there are approximately 140,000 patients diagnosed with ADPKD in the United States, the majority of whom will experience kidney failure and need dialysis or transplantation to prevent death.

[5] Palladio obtained the license to lixivaptan in July of 2016 when it acquired Cardiokine, Inc. from Chiesi USA, Inc. and, in connection with that acquisition, acquired the license to from Wyeth (now Pfizer) for lixivaptan. Centessa then acquired lixivaptan on January 23, 2021.

40. There is no cure for ADPKD. There is currently only one FDA-approved drug indicated to slow kidney function decline in ADPKD patients—JYNARQUE (tolvaptan). Tolvaptan belongs to the same class of drugs as lixivaptan and has the same mechanism of action in blocking the action of vasopressin at its receptors. Like lixivaptan, tolvaptan was first investigated for the treatment of hyponatremia (though, unlike lixivaptan, tolvaptan was ultimately approved by the FDA for this indication in 2009). JYNARQUE (tolvaptan)—the brand name for the ADPKD indication—was approved by the FDA in 2018 and is currently marketed under a REMS program and sold with a blackbox warning due to the risk of liver injury. This risk, according to the Registration Statement, severely limited the marketability of the drug.

41. As JYNARQUE (tolvaptan) carried a significant risk of liver toxicity in ADPKD patients, there is potentially a large untapped market for a drug that could treat ADPKD without harming the liver. Centessa touted lixivaptan as that drug, stating in the Registration Statement that:

> We believe that lixivaptan may offer similar therapeutic activity in treating ADPKD as compared to tolvaptan while avoiding DILI associated with tolvaptan use in this patient population.

This differentiation in safety profile compared to tolvaptan was key to the marketability—and profitability—of the drug and formed the basis for a significant portion of the valuation of Centessa.

42. At the time of the IPO, the potential success of lixivaptan as a differentiated treatment for ADPKD made up the vast majority of Centessa's valuation.

43. In a June 2021 report, Jefferies initiated a price target for CNTA at $35.00 per share attributable to Centessa's four drug candidates in development as follows:

Lixivaptan	~$4B sales potential	~$28/sh
ZF874	>$2B sales potential	~$5/sh
SerpinPC	$600M peak sales potential	~$1/sh
Imgatuzumab	~$350M sales potential	~$1/sh

44. In its June 2021 report, Jefferies noted that, were lixivaptan trials to be unsuccessful, the price target would fall to approximately $7.00 per share. In other words, according to Jefferies, nearly 80% of Centessa's value depended on the successful market differentiation of lixivaptan from tolvaptan.

45. In another June 2021 report initiating coverage of Centessa, analysts at Morgan Stanley wrote that a superior liver safety profile compared to tolvaptan would make lixivaptan a "disruptive treatment for ADPKD." Recognizing that lixivaptan's success depended on its purportedly differentiated safety profile, Morgan Stanley analysts observed that "Palladio sees opportunity in the ADPKD space given the validated nature of the vasopressin mechanism ***and the unfavorable safety profile of the only approved therapeutic***. Management's intention is to commercialize a therapeutic, lixivaptan, that leverages the vasopressin antagonism MoA ***without the risk of severe liver injury or death***."

2. Data Cited by Defendants Did Not Support Their Claim That Lixivaptan Would Have a More Favorable Liver Safety Profile from Competitor Drug Tolvaptan

46. Defendants' claims that lixivaptan was likely to have a differentiated liver safety profile from tolvaptan was unsupported by the evidence cited in the Registration Statement. Defendants stated that their claim was based on data from (1) legacy lixivaptan studies in non-ADPKD cohorts conducted by Cardiokine, (2) results from DILIsym, a quantitative systems toxicology modeling tool, and (3) Phase 2 studies conducted by Palladio prior to the IPO—

purportedly noting that no signs of liver toxicity were observed in any of the above studies and modeling. However, the data from these sources provided no useful insight into the safety profile of lixivaptan as compared to tolvaptan. As detailed below, this is because the studies cited by Defendants were either too short in duration to yield meaningful results or involved the wrong patient population to show whether lixivaptan would cause liver injury in ADPKD patients *per se*—the benchmark Defendants point to as being necessary to the marketability of lixivaptan. Reliance on these sources and failure to disclose confounding data from studies involving competitor drug tolvaptan rendered Defendants' statements regarding both the safety profile and commercial prospects of lixivaptan false when made and lacking any reasonable basis.

a. Studies Involving Competitor Drug Tolvaptan Showed No Signs of Liver Injury in Non-ADPKD Patients and Following Exposure Durations of Less Than Three Months

47. Tolvaptan, a competitor drug of lixivaptan, was first approved for the treatment of hyponatremia (low sodium in the blood) in patients with heart failure in 2009. Developed by Otsuka America Pharmaceutical, Inc. ("Otsuka"), tolvaptan is marketed under the brand name Samsca when used for non-ADPKD indications. Prior to approval, long-term *non-ADPKD* trials were conducted in which 2,414 patients received tolvaptan, with 589 subjects exposed to the drug for at least 14 months.[6] No evidence of liver toxicity was observed in any of the non-ADPKD trials.[7] As a result, Samsca was initially approved for marketing without a warning for potential liver injury.[8]

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[6] Watkins, PB, et al., *Clinical Pattern of Tolvaptan-Associated Liver Injury in Subjects with Autosomal Dominant Polycystic Kidney Disease: Analysis of Clinical Trials Database*, DRUG SAF. 2015 Nov.;38(11):1103-13, 1106-07 ("Watkins 2015").

[7] *Id*. at 1112.

[8] *See* FOOD & DRUG ADMIN., *FDA Drug Safety Communication: FDA Limits Duration and Usage of Samsca (Tolvaptan) Due to Possible Liver Injury Leading to Organ Transplant or Death*, https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-

48. In 2007, Otsuka sponsored a clinical trial to investigate the use of tolvaptan for the treatment of ADPKD. The pivotal, randomized, blinded study, called TEMPO 3:4, enrolled 1,445 ADPKD patients, 740 of whom were exposed to tolvaptan for 36 months.[9] During the trial, 35 participants presented with elevated liver enzymes—a sign of liver injury.[10] Of those 35, 16 cases were deemed probable or highly likely to have been caused by exposure to tolvaptan.[11] Importantly, ***none of the tolvaptan-associated signs of injury appeared within the first three months of exposure***.[12]

49. In 2010, Otsuka sponsored an extension ADPKD trial dubbed TEMPO 4:4. In that study, 871 participants from the TEMPO 3:4 study were given open label tolvaptan at the highest tolerated dose for at least 24 additional months.[13] Nine of the 871 participants presented with signs of liver injury.[14] Two of the nine had actually received tolvaptan in the prior TEMPO 3:4 study (the remaining seven received placebos).[15] As with the prior study, ***no signs of liver injury appeared until after the first three months of treatment***.[16]

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limits-duration-and-usage-samsca-tolvaptan-due-possible-liver (Apr. 30, 2013) (updating drug label to limit treatment duration to 30 days following tolvaptan ADPKD trials) ("FDA Drug Communication: Tolvaptan 2013").

[9] U.S. NATIONAL LIBRARY OF MEDICINE, *Tolvaptan Phase 3 Efficacy and Safety Study in Autosomal Dominant Polycystic Kidney Disease (ADPKD) (TEMPO3:4)*, https://clinicaltrials.gov/ct2/show/study/NCT00428948.

[10] Watkins 2015 at 1106.

[11] *Id*. at 1107.

[12] *Id*.

[13] *Id*. at 1104.

[14] *Id*. at 1106.

[15] *Id*.

[16] *Id*. at 1110. Some of the participants with elevated liver enzymes were re-challenged with tolvaptan after their enzyme levels returned to normal. Of this population, liver enzyme levels remained normal in half the participants, while the other half experienced an immediate elevation in enzyme levels. *Id*. at 1110-11.

50. In April 2013, following the reported liver toxicity adverse events in the TEMPO ADPKD trials, the FDA determined that Samsca (tolvaptan) should not be used for longer than 30 days or in patients with liver disease.[17] However, no further limits were placed on the marketing of Samsca.

51. In April 2018, the FDA approved the marketing of JYNARQUE (tolvaptan) for ADPKD. JYNARQUE is designed for long-term use in patients with ADPKD. Unlike Samsca, the FDA required that the drug be sold with a black-box warning for serious and potentially fatal drug induced liver disease ("DILI") due to the open-ended treatment length and unique pathology of ADPKD raising the risk of liver toxicity. As a result, JYNARQUE (tolvaptan) is only available through a Risk Evaluation and Mitigation Strategy ("REMS") program, which has significantly limited the available market for this drug and poses a barrier to market adoption of the drug.[18] Indeed, as Centessa disclosed in the Registration Statement: "[l]iver toxicity is cited as a major deterrent to using tolvaptan for many patients." In addition to limiting the number of patients eligible for treatment, the additional burdens placed on healthcare providers and patients from the REMS program is cited in the Registration Statement as one reason why "less than half of patients who are considered good candidates for tolvaptan are actually prescribed the drug."

[17] FDA Drug Communication: Tolvaptan 2013, *supra* n. 7.

[18] A REMS is a drug safety program required by the FDA for certain drugs with serious side effects. The purpose of the program is to improve patient safety and help ensure that the potential benefits of the drug are not outweighed by the side effects. For example, a REMS program may require that the drug be administered in-person at a medical center or distributed only through a specialty pharmacy, or it may limit treatment to a subset of patients who meet certain safety criteria. A REMS program can therefore significantly limit the size of the market for a given drug, affect reimbursement by third-party payers such as insurers, and add to the expense of a drug's marking and distribution.

b. The Non-ADPKD Studies Involving Lixivaptan Were of Insufficient Exposure Duration and Involved the Wrong Patient Population

52. The non-ADPKD legacy lixivaptan studies conducted by Cardiokine, which showed no liver toxicity signals in non-ADPKD populations, were cited by Defendants in the Registration Statement as providing "the most useful safety data for the current development program in ADPKD." However, the data provided from these non-ADPKD studies did not support the safety profile of lixivaptan when compared to tolvaptan in ADPKD populations. Though Defendants touted in the Registration Statement that 36 non-ADPKD clinical trials were conducted where "[a] total of 1,673 subjects received at least one dose of lixivaptan[,]" these studies were too short in duration and targeted the wrong population to be indicative of potential liver toxicity in ADPKD populations.

53. As demonstrated by the tolvaptan trials, liver toxicity signals only appear in patients with ADPKD **and** who were exposed to the vaptan for at least three months. The legacy lixivaptan trials, which targeted *non*-ADPKD populations and had a mean exposure duration ***of just 27.5 days***, did not show any differentiated safety data from the non-ADPKD tolvaptan trials—both vaptans had the same number of liver toxicity adverse events: zero.

54. Accordingly, the safety data from these non-ADPKD legacy lixivaptan trials provided no insight into the safety profile of lixivaptan in ADPKD patients.

c. DILIsym Simulations Were Not Reliable Because They Overlooked a Key Cause of DILI, Were Not Specific to ADPKD, and Were Too Short

55. The DILIsym simulations cited by Defendants in the Registration Statement as supportive of lixivaptan's differentiated safety profile were similarly unreliable.

56. First, DILIsym's lixivaptan modeling did not account for a key driver of tolvaptan-induced DILI: adaptive immune responses. The kind of DILI observed in the tolvaptan trials was

"idiosyncratic hepatotoxicity," which frequently results from "adaptive immune" attacks on the liver.[19] But the DILIsym lixivaptan modeling did not account for adaptive immune responses. Indeed, in a 2019 article, Paul B. Watkins ("Watkins"), Director of the DILIsym Initiative and Chairman of the DILIsym Scientific Advisory Board, noted that "[i]t is increasingly appreciated that delayed, idiosyncratic hepatotoxicity is frequently the result of an adaptive immune attack on the liver," and that "***until adaptive immune mechanisms are incorporated into DILIsym, the model cannot be considered reliable to assess idiosyncratic DILI liability***."[20]

57. A Palladio-sponsored research study cited by the Registration Statement also acknowledged as much, observing that "[i]t has been proposed that an adaptive immune-mediated attack plays a role in tolvaptan-mediated toxicity. DILIsym v6A does not represent the adaptive immune system and, as such, cannot determine with absolute certainty that an adaptive immune mechanism would not play a role in the case of lixivaptan as well."[21]

58. Second, the DILIsym lixivaptan simulations, like the legacy lixivaptan studies for the hyponatremia indication, did not address the ADPKD population. As above, the tolvaptan trials demonstrated an increased risk of DILI only in study participants with ADPKD, but not in non-ADPKD subjects. The simulated populations, or "SimPops," in the lixivaptan simulations, however, were "created based on normal healthy volunteer studies."[22] ADPKD patients were not represented. DILIsym's predictions, therefore, were inapplicable to ADPKD. Indeed, in a post-

[19] Watkins 2015 at 1110-1.
[20] Watkins, PB, *The DILI-sim Initiative: Insights into Hepatotoxicity Mechanisms and Biomarker Interpretation*, CLIN TRANSL SCI. 2019 Mar;12(2):122-129. doi: 10.1111/cts.12629. PMID: 30762301; PMCID: PMC6440570 ("Watkins 2019").
[21] Woodhead, J.L., et al., *Comparison of the Hepatotoxic Potential of Two Treatments for Autosomal-Dominant Polycystic Kidney Disease Using Quantitative Systems Toxicology Modeling*, PHARMACEUTICAL RESEARCH (2020) 37:24 ("Woodhead 2020").
[22] Woodhead 2020 at 2.

mortem blog post published after Centessa's decision to terminate development of lixivaptan for ADPKD, Watkins wrote, "[i]t is important to note that this [ALERT] study only enrolled ADPKD patients who had terminated treatment with tolvaptan due to liver toxicity…. Therefore, DILIsym prediction that the [sic] lixivaptan is safer for the liver than tolvaptan ***has not been tested***."[23]

59. Third, the DILIsym lixivaptan simulations were too short. Where the duration modeled in the tolvaptan DILIsym simulations was 180 days,[24] the lixivaptan simulated exposure duration was only 12 weeks—or 84 days.[25] The earliest onset of threshold-achieving liver enzyme elevations in the human tolvaptan trials, meanwhile, was at 90 days of exposure.[26] Accordingly, DILIsym did not support the claim that lixivaptan was less likely to cause liver toxicity than tolvaptan in ADPKD subjects.

d. Palladio-Sponsored Phase 2 ADPKD Trials Did Not Provide Useful Data Because Exposure Duration Was Too Short to Cause DILI and the Study Population Too Small to Provide Rigorous Data

60. The Phase 2 trials conducted by Palladio also did not provide any data upon which Defendants could reasonably rely to evaluate the comparative safety profile of lixivaptan. The ELiSA Study, a phase 2, open-label study, enrolled just 31 ADPKD patients and treated the subjects for just 7 days—far too few to provide rigorous data and far too short to show evidence of liver toxicity. Although the study was partly designed "to guide appropriate lixivaptan dosing recommendations," in the Registration Statement, Defendants cited the results as supportive of

[23] Watkins, PB, *An Update on the Comparison of Lixivaptan's Liver Safety Profile*, SIMULATIONS PLUS (June 17, 2022) ("DILIsym June 17, 2022 Blog Post").
[24] Woodhead JL, et al., *Application of a Mechanistic Model to Evaluate Putative Mechanisms of Tolvaptan Drug-Induced Liver Injury and Identify Patient Susceptibility Factors*. TOXICOL SCI. 2017 JAN;155(1):61-74, 66 ("Woodhead 2017").
[25] Woodhead 2020 at 11, Table 7.
[26] Torres, Vincente, et al., *Tolvaptan in Later-Stage Autosomal Dominant Polycystic Kidney Disease*, N ENGL J MED 2017; 377:1930-1942 DOI:10.1056/NEJMOA1710030 (November 16, 2017), Figure 3 (triangles indicate first instances of threshold-achieving liver elevation).

their claims regarding the purported positive safety profile of the drug, noting that the data from ELiSA showed "a good tolerability profile and ***AEs that are consistent with previous [non-ADPKD] studies***."[27]

C. Centessa Struggles to Recruit Participants for Its Lixivaptan Trial

61. In September 2020, Centessa began recruiting for the Phase 3a ALERT safety study to evaluate the safety profile of lixivaptan in patients who previously treated with tolvaptan but had to permanently discontinue treatment due to "abnormal liver chemistry." [28] Though not a registrational study itself, the ALERT study was a Phase 3 study and was intended to evaluate whether the safety profile of the drug would support initiating the registrational Phase 3 ACTION Study. Palladio designed the study as an open label, repeat dose study where up to 50 patients would be enrolled and treatment would be provided at the maximum tolerated dose level for up to 52 weeks.

62. According to the Registration Statement, the first patient was dosed in November 2020. However, as Defendants later disclosed, only two subjects had received their first lixivaptan dose at the time of the IPO—approximately nine months after the enrollment began for the ALERT study.[29] Centessa's struggles with enrollment indicated a lack of interest in the treatment from both ADPKD patients and practitioners and undermined Centessa's representations of lixivaptan's

[27] Palladio also conducted an open-label, single-arm Phase 2 study called PA-103. The study involved a single ADPKD subject with abdominal pain who previously treated with tolvaptan but had to discontinue due to liver injury. Defendants note that "the subject completed 415 days of treatment with lixivaptan without any evidence of liver injury[,]" but acknowledged that the size of the study limited the usefulness of the data.

[28] U.S. NATIONAL LIBRARY OF MEDICINE, *Safety of Lixivaptan in Subjects Previously Treated with Tolvaptan for Autosomal Dominant Polycystic Kidney Disease (ALERT)*, https://clinicaltrials.gov/ct2/history/NCT04152837.

[29] In a press release dated December 14, 2021, Defendants revealed that only four patients had enrolled in the study as of December 3, 2021. Based on information regarding the treatment duration of each participant at the time, Plaintiffs were able to extrapolate that only two had been enrolled and dosed at the time of the IPO on May 28, 2021.

potential clinical and commercial prospects. Yet Defendants did not disclose these enrollment challenges in the Registration Statement.

IV. DEFENDANTS' MATERIALLY FALSE STATEMENTS IN THE REGISTRATION STATEMENT

63. In connection with the Centessa IPO, Defendants made two categories of false and/or misleading statements: (a) statements about the safety profile of lixivaptan; and (b) statements about the clinical and commercial prospects for lixivaptan.

A. Statements About the Safety Profile of Lixivaptan

64. Defendants made a number of statements regarding the purported differentiated safety profile of lixivaptan as compared to tolvaptan throughout the Registration Statement, citing to non-applicable, unreliable data in support of Defendants' stated belief:

> **We believe lixivaptan has the potential to deliver similar efficacy benefits to tolvaptan**, which is currently indicated for a subset of ADPKD patients, **with a differentiated safety and tolerability profile that may enable access and therapeutic benefit to a broader set of patients.**
>
> * * *
>
> **We believe the potential of lixivaptan in ADPKD is supported by data to date, which includes extensive data from a quantitative-systems toxicology modeling tool, clinical development in a different indication as well as preclinical and clinical studies in ADPKD.**
>
> * * *
>
> **We believe that lixivaptan may offer similar therapeutic activity in treating ADPKD as compared to tolvaptan while avoiding the DILI associated with tolvaptan use in this patient population.**
>
> * * *
>
> **Lixivaptan's development program for ADPKD builds on a historical, extensive development program conducted by our licensors in investigating lixivaptan for the treatment of hyponatremia**. This work included 36 completed clinical studies in which more than 1,600 subjects were dosed with lixivaptan, **the results from which we believe support lixivaptan's activity on key measures believed to be important for ADPKD**. In addition, **no lixivaptan-related liver**

> **toxicity was noted in a safety assessment conducted for potential hepatotoxicity in this previous development program.**
>
> Prior to administering lixivaptan to ADPKD patients, Palladio studied lixivaptan's liver safety profile, as compared to tolvaptan, by utilizing DILIsym, a state-of-the-art, predictive, quantitative systems toxicology modeling tool developed by the DILIsym Consortium in collaboration with the U.S. FDA and industry partners. **DILIsym representations predicted that lixivaptan is not likely to cause DILI and may be better tolerated than tolvaptan with respect to the mechanisms of liver toxicity currently represented in DILIsym.**
>
> * * *
>
> Palladio has completed a Phase 2 clinical trial, designated the ELiSA Study (Evaluation of Lixivaptan in Subjects with ADPKD) …. **Lixivaptan was well tolerated** at the doses given, with adverse events (AEs) **consistent with previous studies in non-ADPKD patients**. **No liver toxicity signals were noted.**
>
> Palladio has also completed a clinical study in a single subject with intractable pain due to ADPKD who was required to discontinue tolvaptan treatment due to clinically significant abnormalities in serum [ALT], a sign of liver toxicity, on each of three sequential attempts to initiate treatment with tolvaptan. The patient was subsequently treated with lixivaptan for more than 14 months with no abnormalities in ALT or other liver chemistry tests.
>
> * * *
>
> **[W]e believe results from PA-102 [Phase 2 ELiSA Study] suggest that lixivaptan may be a potent vasopressin V2 receptor antagonist … with a good tolerability profile and AEs that are consistent with previous studies**.

65. The above statements were materially false and misleading and/or lacked a reasonable basis when made because prior studies and the DILIsym analysis did not support Defendants' claim that lixivaptan was a safer alternative to tolvaptan. In fact, as shown by prior studies with tolvaptan (Section III.B.2.a, *supra*), liver injury from vaptans in patients with ADPKD does not typically occur until the patient has been treated with the drug for at least three months. The legacy lixivaptan hyponatremia studies Defendants cite in the Registration Statement, on the other hand, involved non-ADPKD participants and had a mean exposure duration of just 27.5 days.

Thus, these studies had little relevance to the safety profile of lixivaptan in treating ADPKD—lixivaptan trials for the hyponatremia indication did not implicate DILI risk at all, and the studies were, in any event, too short to provide any meaningful support.

66. DILIsym likewise did not provide a reasonable basis for Defendants' assertions; DILIsym did not model for adaptive immune responses—a common cause of idiosyncratic DILI, the SimPop consisted of non-ADPKD patients, and the simulated exposure duration to lixivaptan was half of the exposure duration in the tolvaptan DILIsym simulation. Thus, Defendants' statements were false and lacked any reasonable basis.

67. Defendants' statements regarding the non-ADPKD lixivaptan legacy studies were especially misleading, given the significantly shortened duration of treatment indicated for hyponatremia and the lack of evidence that liver toxicity is an issue in non-ADPKD populations. In the Registration Statement, Defendants stated:

> Palladio considers the legacy studies in healthy volunteers, including PK studies, drug interaction studies, a renal insufficiency study and a thorough QTc study, **to provide the most useful safety data for the current development program in ADPKD. Lixivaptan was generally well tolerated in these studies without identification of any clinically significant safety signals.**
>
> Following its acquisition of Cardiokine in July 2016, Palladio conducted a safety assessment for potential hepatotoxicity in the Cardiokine hyponatremia program. **No lixivaptan-related liver toxicity was identified.**

68. The above statements were materially false and misleading when made because the data cited by Defendants did not support the claim that lixivaptan had a differentiated safety profile from tolvaptan. Specifically, Defendants did not disclose that clinical trials involving tolvaptan in ADPKD patients—the only drug currently approved by the FDA to treat slowing kidney function in ADPKD patients and to which Centessa compared lixivaptan's safety profile—did not show signs of liver injury until a minimum of three months into treatment and that the legacy lixivaptan

hyponatremia trials had a mean duration of drug exposure of just 27.5 days. Defendants also failed to disclose that *non*-ADPKD tolvaptan trials showed no signs of liver toxicity, despite patients taking the drug for a minimum of 14 months—indicating that liver toxicity is not a risk in non-ADPKD patients. In fact, unlike for ADPKD, the FDA did not require a REMS program or blackbox warning for tolvaptan when used for hyponatremia. This omission was especially misleading because Defendants cited the non-ADPKD lixivaptan clinical trials as "the most useful safety data" supporting its belief of lixivaptan's differentiated safety profile, though the trials were of an inadequate duration to provide any insight into the level of liver toxicity at three months or longer and involved a population not susceptible to vaptan-induced DILI, as evidenced by tolvaptan trials in non-ADPKD cohorts which did not show DILI risk.

69. The above statements were also misleading because Defendants failed to disclose that DILIsym, the quantitative systems toxicology tool utilized by Centessa to compare lixivaptan to tolvaptan, was too short in duration and did not model the adaptive immune response—one of the hypothesized causes of liver injury in patients previously treated with tolvaptan. The adaptive immune system creates immunological memory, which causes enhanced responses to familiar pathogens. The kind of DILI observed in the tolvaptan trials was "idiosyncratic hepatotoxicity," which frequently results from "adaptive immune" attacks on the liver. DILIsym was therefore an inadequate predictor of liver toxicity in lixivaptan.

70. Finally, Defendants failed to disclose that the Phase 2 ELiSA study conducted by Palladio did not provide a reasonable basis for their belief in the safety profile of lixivaptan because the duration of the treatment was too short (only 7 days) and the study population too small (only 31 patients) to provide reliable safety data.

71. Without this additional information, a reasonable investor would be led to believe that Defendants' statements about lixivaptan's safety profile were adequately supported by the specific data cited by Defendants, thereby preventing investors from adequately assessing the risk that further clinical data would show lixivaptan was in fact no safer than the current drug on the market, tolvaptan.

72. In addition, the risk factors listed in the Registration Statement were themselves misleading. Specifically, Defendants stated:

> **Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials**.
>
> * * *
>
> The results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials.
>
> * * *
>
> **[O]ur belief in the therapeutic potential of lixivaptan is based, in part, on experiences of Cardiokine in its development of this molecule for a hyponatremia indication, which included over 30 clinical trials**.

73. The above statements were materially misleading when made because a reasonable investor would believe that the preclinical studies and legacy non-ADPKD trials were adequately designed to provide useful data on the safety profile of lixivaptan—especially with respect to the "over 30 clinical trials" conducted by Cardiokine for a hyponatremia indication. However, as noted above, the mean duration of exposure in the legacy non-ADPKD trials was just 27.5 days—an inadequate amount of time for liver toxicity to develop and be observed—and involved non-ADPKD patients, whom tolvaptan studies have shown did not develop liver toxicity, even after exposure to vaptans for 14 months. Therefore, these legacy studies were an inaccurate and inadequate predictor of safety and tolerability in lixivaptan.

B. Statements Regarding the Clinical and Commercial Prospects for Lixivaptan

74. Defendants also made a series of misleading statements regarding the clinical and commercial prospects of lixivaptan, underplaying the weak demand for the drug by emphasizing the size of the potential market, while failing to disclose that data did not show that lixivaptan was a safer alternative to tolavaptan and that Centessa was struggling to enroll patients in its ongoing Phase 3 ALERT safety study—an indication of a lack of interest in the treatment from both ADPKD patients and practitioners.

75. While highlighting the size of the patient population in the U.S. and noting that potential liver toxicity may be limiting market adoption of tolvaptan in patients with ADPKD, Defendants repeatedly pointed to unreliable data from legacy non-ADPKD studies and DILIsym to support their belief that lixivaptan would have a differentiated safety profile from tolvaptan, and therefore would not suffer the same barriers to market adoption. Yet, at the time of the IPO, Defendants' contention that lixivaptan was a safer alternative lacked any reasonable basis. Thus, Centessa was already facing market adoption issues as it struggled to enroll patients in its ongoing Phase 3 ALERT safety trial—notwithstanding the Company's claims about lixivaptan's safety profile.

76. In its Registration Statement, Defendants pointed to the progress the Company had purportedly made on its lixivaptan development program, noting that the ALERT study was "ongoing," with "[t]he first patient … dosed in November 2020" and stating that "**[u]p to 50 subjects will be enrolled and treated**." The Registration Statement further stated that Centessa would begin its pivotal ACTION trial after "evaluat[ing] … the on-going [ALERT Study] results" to determine if the data "**continue to support**" the Company's view of lixivaptan's safety profile, and anticipated dosing the first patient in the ACTION study in early 2022.

77. A reasonable investor, when reading the Registration Statement as a whole, would understand the above statements to indicate that, absent an adverse event, unlike tolvaptan, lixivaptan would likely be readily accepted into an expanded market. In truth, Centessa was already facing issues with market acceptance, having only enrolled two patients between the start of the enrollment in September 2020 and the date of the Registration Statement, April 21, 2021.

78. The risk factors disclosed in the Registration Statement were similarly false and misleading. For example, the Company warned that "challenges" in enrollment could interfere with clinical development and may even lead to a discontinuation of trials, when that risk had already materialized:

> **We may encounter substantial delays or *challenges in the initiation*, conduct or completion *of our clinical trials***, and the results of clinical development are uncertain.
>
> ***
>
> **Events that may prevent successful or timely completion of clinical development include … delays** in opening a sufficient number of clinical trial sites and **recruiting an adequate number of suitable patients to participate in our clinical trials….**
>
> ***
>
> **The start or end of a clinical study is often delayed or halted due to** changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, **slower than anticipated patient enrollment…. For instance, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial.**

79. The above statements were misleading because Defendants failed to disclose that the risk of enrollment problems had already materialized at the time the statements were made. By the time of the IPO, Centessa had only enrolled two patients in the ALERT trial over a nine-month period, indicating a lack of interest and willingness to risk participation in the trial.

V. POST-IPO EVENTS

80. On June 2, 2022, Defendants issued a press release announcing Centessa's decision to discontinue clinical development for lixivaptan for ADPKD following a "recent observation of

[ALT] and [AST] elevations in one subject in the ALERT study." The press release stated, in relevant part:

> The ALERT Study was designed to help provide an early assessment of the safety profile of lixivaptan in ADPKD patients who previously experienced liver chemistry abnormalities while treated with tolvaptan, the only FDA approved therapy for ADPKD. In assessing the recent data from a subject in the ALERT Study, we believe that lixivaptan is unlikely to achieve the differentiated safety and tolerability profile Centessa required for further development of the program.

81. Jefferies called the discontinuation "[u]nexpected[]" and "a big disappointment." A Jefferies report released that day downgraded Centessa stock from "buy" to "hold" and from a $37 per ADS valuation to $4 per ADS. The report stated in part, "[s]hortly after starting Ph3, discontinuation of lead asset/lixivaptan in a kidney disease/ADPKD comes as a big disappointment, particularly with recent discontinuation of other programs. Lixivaptan accounted for ~80% of our prior valuation."

82. On June 2, 2022, Centessa's ADS price fell $1.25, or 27.78%, to close at $3.25 per share on June 2, 2022.

VI. CLASS ACTION ALLEGATIONS

83. Plaintiffs bring these claims individually and on behalf of all persons and entities other than Defendants that purchased or otherwise acquired Centessa ADSs pursuant or traceable to the Registration Statement issued in connection with the Company's IPO conducted on or about May 28, 2021

84. Excluded from the Class are: (a) Defendants and their immediate families; (b) current and former directors or officers of Centessa or any of its predecessors or subsidiaries; and (c) any entity controlled, majority-owned or wholly owned, or affiliated with any of the above.

85. The members of the Class are so numerous that joinder of all members of the Class is impracticable. The Company's securities were actively traded on the NASDAQ. While the exact

number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are likely thousands of members in the proposed Class. Plaintiffs base this belief, in part, on the fact that Centessa issued 16.5 million ADSs in the IPO and traded an average of 122,219 shares per week since the IPO. Record owners and holders may be identified from records maintained by the Company, its transfer agents, and brokers, and may be notified of the pendency of this Action by mail, using the form of notice customarily used in securities class actions.

86. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. These common questions include the following:

a. Whether Defendants made inaccurate statements and/or omitted material information to investors in the Registration Statement;

b. Whether Defendants' misrepresentations and omissions violated federal securities laws; and

c. Whether Defendants' misrepresentations and omissions were material.

87. Plaintiffs' claims are typical of the claims of all members of the Class, as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal securities laws, and all assert the same legal claims arising out of the same conduct.

88. Plaintiffs will fairly and adequately protect the interests of the members of the Class. Plaintiffs have no interests antagonistic to the Class and have retained highly regarded counsel experienced in securities litigation.

89. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because joinder of all claims is impracticable. Further, as the

damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation may make it impossible for those Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this Action as a class action.

VII. NO STATUTORY SAFE HARBOR

90. None of the above misstatements or omissions were protected by the safe harbor provision of the Private Securities Litigation Reform Act of 1995 ("PSLRA") because they fall outside the scope of the safe harbor provision.

91. Alternatively, the misrepresentations and omissions alleged above in connection with Centessa's IPO, including but not limited to the statements contained within or incorporated by reference into the Registration Statement, were subject to the exception to the safe harbor provision for "statements made in connection with an initial public offering." 15 U.S.C. §78u-5(b)(2)(D).

VIII. CAUSES OF ACTION

A. Count I – Violations of Section 11 of the Securities Act Against Centessa, the Individual Defendants and the Underwriter Defendants

92. Plaintiffs restate and reallege each above allegation as though fully set forth herein.

93. This Count is asserted against all Defendants for violations of Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of Plaintiffs and all members of the Class, who purchased or otherwise acquired Centessa securities pursuant or traceable to the IPO.

94. This count alleges strict liability and negligence and does not sound in fraud. Plaintiffs expressly disclaim any allegations of fraud or fraudulent conduct or motive with respect to this Count.

95. Centessa is the issuer of the securities issued in the IPO. All of the Individual Defendants signed or authorized their signatures on the Registration Statement. As such, Defendants are all strictly liable for each false and misleading statement contained therein or material fact necessary to make the statements contained therein not false or misleading omitted therefrom, including for innocent misrepresentations.

96. The Individual Defendants were all officers or directors of Centessa and consented to be identified as such in the Registration Statement. Therefore, each also had a duty to make a reasonable investigation into the statements contained in the Registration Statement to ensure that said statements were true and did not omit any material fact required to be stated in order to make said statements not false or misleading. In the exercise of reasonable care, the Individual Defendants should have known of the material misstatements and omissions contained in the Registration Statement. As such, each Individual Defendant is liable to Plaintiffs and the Class for negligent misrepresentation.

97. The Underwriter Defendants are strictly liable for the false and misleading statements in the Registration Statement. The Underwriter Defendants assisted Centessa and the Individual Defendants in planning the IPO and were required to conduct an adequate and reasonable investigation into the business and operations of the Company, a process known as a "due diligence" investigation, in order to participate in the IPO. The Underwriter Defendants failed to do so, in part due the rapid pace at which the IPO was conducted, mere months after Centessa's formation.[30]

[30] Senior, Melanue, *Innovators Take Cover as Market Bubble Bursts*, NAT BIOTECHNOL. 2022 Apr;40(4):450-457.

98. During the course of their investigation, the Underwriter Defendants had continual access to confidential corporate information concerning Centessa's drug pipeline and financial prospects. In addition, both of the Underwriter Defendants employed analysts with specific expertise in biopharmaceutical valuations. In addition, agents of the Underwriter Defendants met with Centessa's lawyers, management, and top executives in connection with the IPO. During these sessions, the Underwriter Defendants, Centessa, and the Individual Defendants made joint decisions regarding: (a) the terms of the IPO, including the price at which Centessa ADSs would be sold to the public; (b) the strategy to best accomplish the IPO; and (c) the information to be included in the Registration Statement. As a result of those contacts and communications between the Underwriter Defendants' representatives and Centessa's management and top executives, the Underwriter Defendants, in the exercise of reasonable care, should have known of the material misrepresentations contained in the Registration Statement and alleged herein.

99. Plaintiffs and the Class purchased or acquired Centessa ADSs without knowledge of the misstatements and omissions alleged herein. Plaintiffs and each member of the Class were thus damaged by Defendants' material misstatements and omissions.

B. Count II – Violations of Section 15 of the Securities Act Against the Individual Defendants

100. Plaintiffs restate and reallege each above allegation as though fully set forth herein.

101. This Count is asserted against the Individual Defendants for violations of Section 11 of the Securities Act, 15 U.S.C. §77o, on behalf of Plaintiffs and all members of the Class, who purchased or otherwise acquired Centessa ADSs pursuant or traceable to the IPO.

102. Each of the Individual Defendants was involved in the day-to-day activities of Centessa prior to the IPO and was involved in preparing and reviewing the Registration Statement, and each had the ability to control the contents thereof. By reason of their senior management and

leadership positions, the Individual Defendants each possessed the power and authority to control the contents of Centessa's reports to the SEC, press releases, and other public statements and presentations. These Defendants had the power to direct the actions of and exercised the same to cause the Company to engage in the unlawful acts and conduct complained of herein.

103. Plaintiffs and other members of the Class acquired Centessa ADSs without knowledge of the misstatements and omissions alleged herein. Plaintiffs and the Class were thus damaged by the primary violations of the Company. By virtue of their conduct alleged herein, and their status as control persons of the Company, these Defendants are secondarily liable to Plaintiff and the Class for the primary violations of Centessa.

IX. PRAYER FOR RELIEF

104. WHEREFORE, Plaintiffs demand judgment in favor of Plaintiffs and the Class, and against Defendants, as follows:

a. Declaring that this action is properly maintainable as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as Class Representatives and Co-Lead Counsel as Class Counsel;

b. Awarding Plaintiffs and the Class compensatory damages;

c. Awarding Plaintiffs and the Class pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, expert witness fees, and other expenses;

d. Awarding extraordinary, equitable, and injunctive relief as permitted by law, equity, and the federal statutory provisions sued hereunder, and any appropriate state law remedies;

e. Granting Plaintiffs leave to amend the complaint to conform to the evidence; and

f. Awarding such other relief as this Court may deem just and proper.

X. JURY TRIAL DEMAND

105. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs and the Class demand a trial by jury.

Date: February 10, 2023

/s/ Shannon L. Hopkins

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